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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/039,927	03/16/1998	HENRY A. LESTER	A-63098-1/RF	1215

7590

07/12/2005

FLEHR HOHBACH TEST ALBRITTON & HERBERT
FOUR EMBARCADERO CENTER
SUITE 3400
SAN FRANCISCO, CA 94111

EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/039,927

Applicant(s)

LESTER ET AL.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,20,21,23 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 20, 21, 23, 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendments filed 29 April 2005 has been entered. Claims 1-17, 19, 20, 22 and 24 has been cancelled. Claims 18, 20, 21, 23 and 25-30 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 29 April 2005 have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC 112

4. Claims 18, 20, 21, 23 and 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25, 26 and 27 recite the term "hybridize under low stringency conditions" which is a relative term whose metes and bounds are not clear. Hybridization conditions require specific salt and temperature as well as specific wash conditions without which the metes and bounds of the structure of the nucleic acid which results in the low stringency hybridization conditions are not clear.

Claims 18, 20, 21, 23 and 27-30 recite the term "at least about 50%" or at least about 75%" whose metes and bounds are not clear because it is not clear where is the

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lower boundary of at least about a specific percentage.

5. Claims 25, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The reason for the rejection has been set forth in the previous office action.

Claims encompass nucleic acid which "hybridize under low stringency conditions" nucleic acid encoding Kir 3.0 channels used in the method assay. However, one skilled in the art cannot envision all the various species of Kir 3.0 channel subunits because under low stringency conditions the nucleic acids which would hybridize is an enormous number and variety. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the genus of Kir3.0 channels structure cannot be envisioned.

Priority

6. Claims 25 is non-obviously broader than claims in the parent application 08/066,371 and thus are not entitled to benefit of the earlier filing date.

The reason for the rejection has been set forth in the previous office actions.

Claim Rejections - 35 USC 102

7. Claim 25 remains rejected under 35 U.S.C. 102(b) as being anticipated by Yatani et al.((12); Science, 1987) with evidence by Krapivinsky et al.(Nature, 1995).

The reason for the rejection has been set forth previously.

Applicants argue that Yatani does not teach cell claimed because it is a patch clamp. However, the isolated cells of Yatani are provided with heteromeric subunits to form the inward rectifier channels prior to the patch clamp thus meeting the amended claim limitation. Furthermore, the nucleic acid which would encode the subunits would inherently hybridize under low stringency conditions because the all nucleic acids which have regions of homology would hybridize under low stringency conditions.

8. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Karschin et al.((8); PNAS, 1991) with evidence by Krapivinsky et al.(Nature, 1995).

The reason for the rejection has been set forth previously.

Applicants argue that the potassium channel of Karchin is not conclusively a Kir channel. However, Karchin cardiac myocytes inherently comprise the inward rectifier and encompasses the term Kir potassium channel. Furthermore, the claim limitation only requires the function of an inward K⁺ current.

9. No claims are allowed.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on Monday-Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Michael D. Pak
Michael Pak
Primary Patent Examiner
Art Unit 1646
07 July 2005